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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,876	05/06/2002	Richard Gerardus F. Visser	92750/65	5153

7590 11/22/2005

Amster Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,876	VISSER ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 39-50,54-58.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-50,54-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-50,54-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 51-53 are cancelled. Claims 39-50 and 54-58 are pending and examined.

Rejection of Claims 45, 50 and 55 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments and arguments.

Rejection of Claims 56-58 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments and arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 39-50 and 54-58 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a starch branching enzyme genetic construct and methods of expressing and altering the affinity for starch in plants transformed therewith does not reasonably provide enablement for GBSSI genetic constructs and methods of expressing and altering the affinity for starch in plants transformed therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/24/2005.

Applicant's arguments filed 8/23/2005 have been considered but are not deemed persuasive.

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Applicant asserts that the Filpse reference teaches increased activity of GBBSI in transformed plants resulting in increased amylose and therefore shows that the invention is enabled (response page 8). Applicant fails to acknowledge the context of the increase reported in the Filpse reference. Simply put, over-expression of GBSS did not recover levels of amylose greater than that of the wild type, and thus the invention is not enabled.

Applicant states that one of skill in the art would appreciate that enzymes are limited by availability of substrate and *in vivo* settings by feedback mechanisms; and further states that it would be necessary to rely upon one of skill in the art to enable the invention by performing routine experiments to select the required materials (response page 9). Applicant has provided no working examples that would guide the skilled artisan to make and use the invention.

Given the lack of guidance and working examples in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through a multitude of non-exemplified plants transformed with a genetic construct comprising a polynucleotide encoding a GBSSI enzyme and a bacterial starch binding domain for increases in starch GBSSI affinity to determine how to use the genetic construct comprising a polynucleotide encoding the bacterial starch domain and the GBSSI enzyme and plants transformed therewith.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 102

Claims 39, 41 and 44 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dalmia B. *et al.* Biotechnology and Bioengineering, 1995; Vol. 47 pp. 575-584 in light of GenBank Accession gi: 142654; April 26, 1993. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/24/2005. Applicant's arguments filed 8/23/2005 have been considered but are not deemed persuasive.

Applicant asserts that the construct of the prior art is not suitable for transformation in a plant (response page 10). The claim does not set forth any requirements for what is suitable for transforming a plant other than the elements listed in sections (a) and (b) of the claim. Moreover, the construct set forth in the Dalmia reference would express in the bacterial related genome of the plant plastid and thus claim limitations as broadly stated are met by the reference.

Claims 39, 42-50, 54-57 and 58 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kortstee A. *et al.* The Plant Journal, 1996; Vol. 10, No. 1; pp. 83-90. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/24/2005. Applicant's arguments filed 8/23/2005 have been considered but are not deemed persuasive.

Applicant asserts that Kortstee does not teach a bacterial starch binding domain (response page 10). Bacterial starch binding domains are inherent to bacterial enzymes that make or break the covalent bonds of starch such as the starch branching enzyme from *E. coli* taught by Kortstee encoded by *glgB*, which is made evident by the altered starch branching in the plant transformed therewith.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
November 10, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis